

Serial No.: 10/663,925

Confirmation No.: 2297

Filed: September 16, 2003

For: POLYMERS WITH SOFT SEGMENTS CONTAINING SILANE-CONTAINING GROUPS, MEDICAL DEVICES, AND METHODS

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### Remarks

The Office Action mailed May 25, 2006 has been received and reviewed. Claims 1, 9, 10, 18, 26, 27, and 39 having been amended, and claims 12, 29, and 35-38 having been canceled, without prejudice, the pending claims are claims 1-11, 13-28, 30-34, and 39-40. Claims 1, 18, and 39 have been amended to include language similar to that in claim 12. Reconsideration and withdrawal of the rejections are respectfully requested.

### The 35 U.S.C. §102 Rejections

The Examiner rejected claims 1-17 and 35-36 under 35 U.S.C. §102(b) as being anticipated by Gunatillake327 (WO 99/50327) (US Equivalent 6,437,073). The Examiner also rejected claims 1-17 and 35-36 under 35 U.S.C. §102(b) as being anticipated by Gunatillake863 (WO 99/03863) (US Equivalent 6,420,452). Claims 1-17 having been amended and claims 35-36 having been cancelled, these rejections are rendered moot. Insofar as they apply to the currently pending claims, they are traversed.

Applicants' claims are directed to a segmented polymer that includes soft segments that are derived from the recited silane-containing compound, wherein each R<sup>3</sup> is independently an unsubstituted straight chain alkylene group that contains more than 4 carbons (e.g., claim 1).

At page 3 of the Office Action the Examiner stated that "the word 'soft' in the present invention is a relative term." While hard and soft are relative terms, the Examiner appears to imply that they are not sufficiently defined. Applicants respectfully disagree. At page 9, lines 3-20, these terms are clearly defined relative to their crystalline and/or amorphous nature as follows:

As used herein, a "hard" segment is one that is either crystalline at use temperature or amorphous with a glass transition temperature above use temperature (i.e., glassy), and a "soft" segment is one that is amorphous with a glass transition temperature below use temperature (i.e., rubbery). A crystalline or glassy moiety or hard segment is one that adds considerable strength and

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higher modulus to the polymer. Similarly, a rubbery moiety or soft segment is one that adds flexibility and lower modulus, but may add strength particularly if it undergoes strain crystallization, for example. ...

As used herein, a "crystalline" material or segment is one that has ordered domains. A "noncrystalline" material or segment is one that is amorphous (a noncrystalline material may be glassy or rubbery). A "strain crystallizing" material is one that forms ordered domains when a strain or mechanical force is applied.

Gunatillake327 is directed to a non-elastomeric polyurethane and Gunatillake863 is directed to an elastomeric polyurethane, wherein the chain extenders are derived from silicon-containing diols. There is no teaching or suggestion of a segmented polymer that includes soft segments that are derived from the recited silane-containing compound (e.g., claim 1), wherein the soft segments are ones that are "amorphous with a glass transition temperature below use temperature (i.e., rubbery)." Applicants explain at page 7, line 32 through page 8, line 13 of their specification that the chain extenders of Gunatillake863 (which are analogous to the chain extenders of Gunatillake327) form hard segments:

The present invention provides advantage in terms of the synthesis and properties of the resultant polymer relative to polymers derived from silane-containing chain extenders, which form hard segments, as described in International Publication No. WO 99/03863. In this latter method, the silane-containing chain extenders in the hard segment improve the compatibility between hard segments and soft segments, which improves the strength of the polymer. In the present invention, silane-containing compounds of Formula I are used in the soft segment to provide such compatibility. These polymers have improved strength using commercially available chain extenders compared to those described in WO 99/03863. Furthermore, it is believed that the properties of the polymers of the present invention are more easily controllable than that of the polymers of WO 99/03863 because the structures of the soft segments are more easily variable using the compounds of Formula I.

Applicants do not understand the Examiner's statement in the Office Action at page 3 that "the extenders containing arylene groups inherently impart hard segments to the polyurethane. However, the particular hard segments mentioned are

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relative hard segments as compared to those extenders containing C1-C12 alkylene radicals." Clarification is requested in view of the fact that one of skill in the art of polyurethane chemistry would understand that a "chain extender" forms a hard segment, which is defined in Applicants' specification (page 9, lines 4-6) as "one that is either crystalline at use temperature or amorphous with a glass transition temperature above use temperature (i.e., glassy)." Furthermore, it is unclear why the Examiner has apparently ignored Applicants' description at page 7, line 32 through page 8, line 13. Applicants request withdrawal of these rejections.

The Examiner rejected claims 1-12, 14-15, 17, and 35-36 under 35 U.S.C. §102(b) as being anticipated by Zdrahala et al. (US 4,647,643). Claim 1 having been amended and claims 12, 35, and 36 cancelled, this rejection is rendered moot. Although the generic structure (Formula I) in Zdrahala et al. refers to the W groups as "divalent linking groups," and disclose alkylene bridges of from 1 to 4 carbon atoms, all the examples are directed to siloxanes. There is no disclosure of segmented polymers wherein each R<sup>3</sup> is independently an unsubstituted straight chain alkylene group that contains more than 4 carbons, as recited in Applicants' claims. Withdrawal of this rejection is respectfully requested.

The Examiner rejected claims 35-36 under 35 U.S.C. §102(b) as being anticipated by Gunatillake971 (WO 00/64971, U.S. Equivalent 2002/0028901). This rejection is rendered moot in view of the cancellation of claims 35 and 36. Applicants have cancelled these claims in the interest of expediting prosecution and reserve the right to pursue these claims in a continuing application.

The Examiner rejected claim 35 under 35 U.S.C. §102(b) as being anticipated by Iwahara (EP 661 332). This rejection is rendered moot in view of the cancellation of claim 35. Applicants have cancelled this claim in the interest of expediting prosecution and reserve the right to pursue this claim in a continuing application.

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**The 35 U.S.C. §103 Rejection**

The Examiner rejected claims 11-12 under 35 U.S.C. §103(a) as being unpatentable over Zdrahala et al. (U.S. 4,647,643). This is respectfully traversed. There is no teaching or suggestion of a segmented polymer that includes soft segments that are derived from the recited silane-containing compound, wherein each R<sup>3</sup> is independently an unsubstituted straight chain alkylene group that contains more than 4 carbons. There is only brief mention of alkylene chains in Zdrahala et al., and all the examples are directed to siloxanes in which R<sup>7</sup> is oxygen. There is no enabling teaching of how to make Applicants' claimed materials in Zdrahala et al. There is no teaching, suggestion, or recognition of the advantages of Applicants' claimed materials in Zdrahala et al.

Although obviousness does not require absolute predictability, at least some degree of predictability is required (M.P.E.P. § 2143.02). Applicants respectfully submit that the standard for obviousness is not that a result might occur; rather, the standard for obviousness is that there has to be a reasonable expectation of success. Further, the reasonable expectation of success must be in the prior art. To establish a *prima facie* case of obviousness, three criteria must be met.

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. M.P.E.P. § 2142 (citations omitted).

These criteria have not been met. Apparently, the Examiner is applying an obvious to try rationale in support of the obviousness rejection, which is not permissible (see, e.g., M.P.E.P. § 2145). Withdrawal of this rejection is respectfully requested.

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**Summary**

It is respectfully submitted that the pending claims 1-11, 13-28, 30-34, and 39-40 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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**CERTIFICATE UNDER 37 CFR §1.10:**

"Express Mail" mailing label number: EV 201876987 US

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The undersigned hereby certifies that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By:

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